

Appendix A

Novartis Survey of Consumers Suffering from Constipation - Summary of Findings -

Methodology

Approximately 40,000 panelists across the United States were invited to participate in a random, cross-sectional, web-enabled survey that addressed issues relevant to Chronic Constipation. The consumer panel was representative of the US population. A 6-question screener identified eligible participants to ensure that they fulfilled the following criteria:

- 18 years or older
- Had to be able to read and write in English
- Must have exhibited symptoms of constipation during the past year as defined by the Rome II criteria
- Must have consulted a physician for constipation symptoms over the past 12 months.
- Must not have been diagnosed with irritable bowel syndrome or organic gastrointestinal disease by a physician
- Must not have been pregnant

A total of 557 qualified respondents completed the survey.

Summary Findings

Three-quarters of surveyed patients (72%) have been suffering from constipation symptoms for five years or less. Eight of 10 respondents (81%) have fewer than five bowel movements in an average week. About a third (34%) has 1-2 bowel movements compared to those with 3-4 bowel movements in an average week accounting for 31% of all surveyed. In contrast, 77% of patients consider five or more bowel movements a week normal.

Straining during bowel movements and lumpy or hard stools are experienced by most patients with 77% and 73% of respondents having those symptoms during at least 12 weeks within the past year, respectively. Sensation of incomplete evacuation is reported by 58%, fewer than 3 bowel movements per week by 47% and a sensation of blockage by 40% - all during at least a 12 week period within the past year.

When presented with a list of constipation symptoms, at least half of all patients rate the following symptoms as "extremely" or "very" bothersome:

- Abdominal pain (60%)
- Rectal pain (53%)
- Bloating (52%)
- Straining (51%)
- Sudden urges to have a bowel movement (51%)

When rating the severity of their symptoms, four out of ten patients rate the following symptoms "extremely" or "very" severe:

- Abdominal pain (44%)
- Hard frequency of stools (41%)

- Infrequent bowel movements (40%)
- Straining (38%)
- Rectal pain (37%)

In terms of impact on quality of life, 51% of respondents point to abdominal pain and 45% to sudden urges to have a bowel movement as the symptoms with a lot or a great deal of negative impact on their quality of life.

Approximately a third of all respondents consider the following symptoms as having a lot or a great deal of impact on their quality of life:

- Bloating (37%),
- Abdominal discomfort (36%),
- Rectal pain (34%),
- Infrequent bowel movements (33%)
- Straining (32%)

80% of patients have tried an OTC product for the treatment of their constipation symptoms at least once since their symptoms started and 37% of all respondents are currently taking an OTC drug. Fiber is the most popular treatment option as 74% of all patients have tried it and 50% are currently taking it. In terms of OTC usage, OTC laxatives are second only to fiber with 70% of patients having tried them and 27% currently using them. About a third of all patients tried OTC enemas (31%) and/or other OTC medications (35%) since their symptoms started.

Prescription drug use is lower with only 35% ever trying prescription drug therapy. Currently 11% of patients take prescription drugs for the treatment of their constipation symptoms. Prescription laxatives are the most widely tried (27%) and used Rx medicines (8%).

Overall, 47% of all patients are not completely satisfied with the treatment currently followed for constipation. 74% cite efficacy and 13% note safety/side effects as the reason for their dissatisfaction. The level of dissatisfaction increases with the increase in the number of symptoms. Four in 10 patients suffering from a combination of constipation and bloating (46%) or constipation and abdominal pain (40%) are not completely satisfied with their therapy followed. In contrast, 56% of patients suffering from abdominal pain/discomfort, bloating and constipation are not completely satisfied with their current therapy.

Patients rate efficacy as the most important factor in their product selection for constipation treatments. At least three-quarters rate the following as extremely or very important:

- Effective relief of constipation (80%)
- Effective in improving the quality of bowel movements (79%)
- Effective in improving the quantity of bowel movements (76%)

Tolerability (73%), predictable response time (73%), the relief of multiple symptoms (71%), ease of use (71%), appropriateness for long-term use (71%) and effectiveness for abdominal pain (70%) are very or extremely important attributes when selecting a constipation treatment for seven in 10 respondents.

From a list of terms, 19% of patients selected recurrent constipation as the most frequently used term by a physician to describe a diagnosis followed by 14% selecting functional constipation and 11% choosing chronic constipation.